

REMARKS

Applicants filed Amendment D on October 2, 2003 in response to the Final Rejection of July 2, 2003. Thereafter, the Examiner issued an Advisory Action on November 7, 2003. Applicants are filing herewith a RCE to enter Amendment D and the arguments made therein. This amendment is in furtherance of Amendment D and is intended to specifically address those issues raised in the Advisory Action.

I. Sole Active Component

In the Advisory Action, the Examiner contends that the amended claims “do not recite wherein a halogenated xanthene is the ‘sole active component.’” Applicants respectfully traverse this objection.

Each of the independent claims is directed to a photodynamic medicament or pharmaceutical composition “consisting of” a halogenated xanthene as the photoactive or active component or use of a halogenated xanthene as the active component. It is well established law that the language “consisting of” in claims means excluding more than traces of other ingredients. Hence, in each of the independent claims, the medicament or pharmaceutical composition consists of a halogenated xanthene as the active component or photoactive component and excludes other ingredients as being either the photoactive or active components. This is clearly the case in each of the independent claims, as illustrated by the relevant sections thereto (emphasis added):

“Claim 1. A topically-applicable photodynamic medicament,
the topically applicable photodynamic medicament *consisting of a
halogenated xanthene as the photoactive component*”

Thus, Claim 1 is directed to a photodynamic medicament consisting of a halogenated xanthene as the photoactive component. Since the medicament is a photodynamic medicament, there would be no other active components (i.e., components capable of eliciting the claimed photodynamic effect.) Similar reasoning applies to Claims 13, 17, 36 and 37, which recite as follows (emphasis added):

“Claim 13. Use of *a halogenated xanthene as the active component* in the preparation of a topical photodynamic medicament ... wherein said halogenated xanthene is a compound selected from the group consisting of”

“Claim 17. Use of *a halogenated xanthene* comprising: topically administering a therapeutically effective amount of *the halogenated xanthene as the photoactive agent*”

“Claim 36. A topically-applicable photodynamic medicament *consisting of a halogenated xanthene as the photoactive component*, wherein said halogenated xanthene is a compound selected from the group consisting of”

“Claim 37. A topically-applicable photodynamic medicament consisting of *a halogenated xanthene* as the active component, wherein said halogenated xanthene is a compound selected from the group consisting of”

Thus, as in the case of Claim 1, Claims 13, 17, 36 and 37 are directed photodynamic medicaments consisting of a single active component (i.e., one halogenated xanthene).

Turning to Claim 21, this claim is directed to a photodynamic pharmaceutical composition consisting of a single photoactive component (i.e., one halogenated xanthene)(emphasis added):

“Claim 21. A photodynamic pharmaceutical composition for topical administration *consisting of a halogenated xanthene as the photoactive component* for treatment using photodynamic therapy,

wherein said halogenated xanthene is a compound selected from the group consisting of”

As in the case of Claims 1, 13, 17, 36 and 37, the claimed composition would not contain other photo active components (i.e., components capable of eliciting the claimed photodynamic effect).

Finally, Claim 32 is directed to a method for photodynamic treatment consisting of topical application of a photodynamic medicament comprising a single active component (i.e., one halogenated xanthene) (emphasis added):

“Claim 32. A method of treating diseased tissue comprising:
topically applying a photodynamic medicament *consisting of a halogenated xanthene as the photoactive component* to or proximate to diseased human or animal tissue, wherein said halogenated xanthene is a compound selected from the group consisting of”

As in the case of the other independent claims, the requisite photodynamic medicament of the claimed method would not contain other photoactive components (i.e., components capable of eliciting the claimed photodynamic effect).

Assuming *arguendo* that the claimed photodynamic medicaments and pharmaceutical compositions contained one or more *non-photoactive active* components (for instance, hypothetically, an additional chemotherapeutic or analgesic ingredient), this would not affect the patentability of the claimed photodynamic medicaments and pharmaceutical compositions, since the scope of the claims is directed to topical photodynamic medicaments and pharmaceutical compositions that contain a single halogenated xanthene as the sole photoactive ingredient. Further, the claims are not directed to medicaments which do not have a halogenated xanthene as the photoactive component (i.e. halogenated xanthene that is only for a non-photodynamic use and none

for photodynamic use). Such scope is consistent with the teachings of the present application which illustrates novel photodynamic medicaments for the halogenated xanthenes but does not presume to encompass all medicaments for such class of molecule.

Therefore, it is respectfully requested that this objection be withdrawn.

II. Reference to Disclosure

In the Advisory Action, the Examiner also objects to Amendment D stating that no reference is made in the amendment for support for the claim amendments. Applicants have the following response to this objection by the Examiner.

Independent Claims 1, 13, 17, 21, 32, 36 and 37 were amended in Amendment D to claim medicaments or other pharmaceutical compositions consisting of a halogenated xanthene as the sole active component (i.e. “consisting of” language). Such amendments were made to bring these claims into conformance with the specification, which clearly describes such medicaments or other pharmaceutical compositions consisting of a single halogenated xanthene as the active component.

In response to the Examiner’s objections concerning claim amendments *viz-a-viz* supporting disclosure, Applicants respectfully provide the following references to the specification. Examples in support of such amendments and the resultant claimed medicaments or other pharmaceutical compositions are found, for example, in the specification as follows:

“The present invention is directed to new photodynamic, topically-applicable medicaments ... wherein a primary active component of such medicaments is a halogenated xanthene. Such halogenated xanthenes discussed *infra* are capable of exhibiting a desirable photodynamic effect when applied to or otherwise delivered to certain human or animal tissues....” [p. 5, lines 2-7, emphasis added]

This passage teaches that a halogenated xanthene is capable of eliciting a photodynamic response (i.e., is useful as the active photodynamic ingredient in a photodynamic medicament). This is further elucidated by the following passage:

"It is thus a preferred embodiment of the present invention that a topically-applicable medicament be produced that contains, as an active ingredient at a concentration of from greater than approximately 0.001% to less than approximately 20%, at least one halogenated xanthene." [p. 6, lines 13-15]

This passage confirms the aforementioned teaching that the claimed medicaments shall contain, as their photoactive ingredient, one or more compounds from the halogenated xanthene class of compound.

The use of a single halogenated xanthene as the sole active ingredient in a photodynamic medicament is further supported by a number of examples provided in the specification, such as the following:

"... applicants have found that application of a cream or solution containing Rose Bengal at a concentration of approximately 0.1% W/V to persistent leg ulcers, followed, after a latency period of 0-72 hours, and more preferably 0-1 hour, by illumination with approximately 10 to 200 J/cm² of continuous or pulsed green light in the 500-600 nm band, leads to substantial or complete healing of such persistent leg ulcers, with little or no side effects in surrounding tissue." [p. 13, lines 9-13]

Similar examples are provided on pp. 14, 15, 16, 17 and 18 of the specification, each illustrating that a photodynamic medicament or other pharmaceutical composition consisting of a single halogenated

xanthene (in this case Rose Bengal) as the sole active component is capable of exhibiting the claimed photodynamic properties.

Taken either alone or together with the remainder of the specification, these passages clearly demonstrate that the halogenated xanthenes exhibit the claimed photodynamic properties as the sole active ingredient in a photodynamic medicament, thereby supporting Applicants' amended independent Claims 1, 13, 17, 21, 32, 36 and 37. Furthermore, applicability of Applicants' claims to the range of halogenated xanthenes cited in these claims is provided, for example, by the list of compounds found on p. 6, line 16 to p. 7, line 2 of the present application.

For at least the aforementioned reasons, Applicants respectfully submit that the claim amendments are appropriately supported by the specification and request that this objection be withdrawn.

III. Intended Use

The Examiner also argues that the term "photoactive component" (and, hence, "photoactive") is an intended use limitation. Applicants respectfully disagree.

Independent Claim 1 is directed to a topically applicable photodynamic medicament consisting of a halogenated xanthene as the active component, wherein said medicament is for treatment of diseases of human and animal tissue. The terms "topically-applicable" and "photodynamic medicament" are not intended uses but rather actual limitations of the claim. As explained in depth in Amendment D, a photodynamic medicament is a well known term and drug to those skilled in the art. It is a thing and has a specific meaning to those skilled in the art. As explained in Amendment D, such a medicament is a clearly different thing to those skilled in the art

than, for instance, an injectable agent such as that described in Goers. Hence, these are terms which breath life into the claim and therefore, recognized under well established law as limitations of the claim.

As discussed in depth in Amendment D, none of the cited references disclose or suggest these limitations of the claims. Hence, independent Claim 1 and those claims dependent thereon are patentable over the cited references.

For similar reasons, the other claims are also patentable over the cited references.

IV. Conclusion

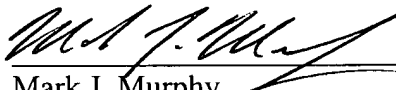
For at least the above-stated reasons and the reasons explained in Amendment D, it is respectfully submitted that the claims of the present application are in an allowable form and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any fee should be due for this response, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

Date: December 2, 2003


Mark J. Murphy
Registration No. 34,225

COOK, ALEX, McFARRON, MANZO,
CUMMINGS & MEHLER, Ltd.
200 West Adams Street, Suite 2850
Chicago, Illinois 60606
(312) 236-8500